What is claimed is:

- 1. An antigenic composition comprising a selected antigen from a pathogenic virus, bacterium, fungus or parasite, or from a cancer cell or tumor cell, or from an allergen, or from an amyloid peptide protein, and an effective adjuvanting amount of the combination of: (1) 3-0-deacylated monophosphoryl lipid A or monophosphoryl lipid A and derivatives and analogs thereof, and (2) a cytokine or lymphokine, or an agonist or antagonist to said cytokine or lymphokine, wherein the combination of adjuvants enhances the immune response in a vertebrate host to said antigen.
- 2. The antigenic composition of Claim 1 where the selected antigen is a polypeptide, peptide or fragment derived from a protein.
- 3. The antigenic composition of Claim 1 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 4. The antigenic composition of Claim 1 where the cytokine or lymphokine is selected from the group consisting of granulocyte macrophage colony stimulating factor and interleukin-12.
- 5. The antigenic composition of Claim 4 where the cytokine or lymphokine is granulocyte macrophage colony stimulating factor.
- 6. The antigenic composition of Claim 5 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 7. The antigenic composition of Claim 6 wh re the cytokine or lymphokine is interleukin-12.
- 8. The antigenic composition of Claim 7 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stabl oil-in-water emulsion.

- 107 -

- 9. The antigenic composition of Claim 1 which further comprises a diluent or carrier.
- 10. The antigenic composition of Claim 9 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 11. A method for increasing the ability of an antigenic composition containing a selected antigen from a pathogenic virus, bacterium, fungus or parasite to elicit the immune response of a vertebrate host, which comprises administering to said host an antigenic composition of Claim 1.
- 12. A method for increasing the ability of an antigenic composition containing a selected antigen from a pathogenic virus, bacterium, fungus or parasite to elicit the immune response of a vertebrate host, which comprises administering to said host an antigenic composition of Claim 9.
- 13. A method for increasing the ability of an antigenic composition containing a selected antigen from a pathogenic virus, bacterium, fungus or parasite to elicit cytotoxic T lymphocytes in a vertebrate host, which comprises administering to said host an antigenic composition of Claim 1.
- 14. A method for increasing the ability of an antigenic composition containing a selected antigen from a pathogenic virus, bacterium, fungus or parasite to elicit cytotoxic T lymphocytes in a vertebrate host, which comprises administering to said host an antigenic composition of Claim 9.
- 15. A method for increasing the ability of an antigenic composition containing a selected cancer antigen or tumor-associated antigen from a cancer cell or tumor cell to elicit a therapeutic or prophylactic anti-cancer effect in a vertebrate host, which comprises administering to said host an antigenic

WO 00/69456

- 108 -

PCT/US00/13156

composition comprising said selected cancer antigen or tumor-associated antigen from a cancer cell or tumor cell, and an effective adjuvanting amount of the combination of: (1) 3-0-deacylated monophosphoryl lipid A or monophosphoryl lipid A and derivatives and analogs thereof, and (2) a cytokine or lymphokine, or an agonist or antagonist to said cytokine or lymphokine.

- an antigenic composition containing a selected allergen to moderate an allergic response in a vertebrate host, which comprises administering to said host an antigenic composition comprising said allergen, and an effective adjuvanting amount of the combination of: (1) 3-0-deacylated monophosphoryl lipid A or monophosphoryl lipid A and derivatives and analogs thereof, and (2) a cytokine or lymphokine, or an agonist or antagonist to said cytokine or lymphokine.
- an antigenic composition to prevent or treat disease characterized by amyloid deposition in a vertebrate host, which comprises administering to said host a polypeptide, peptide or fragment derived from amyloid peptide protein, or an antibody thereto, and an effective adjuvanting amount of the combination of:

 (1) 3-0-deacylated monophosphoryl lipid A or monophosphoryl lipid A and derivatives and analogs thereof, and (2) a cytokine or lymphokine, or an agonist or antagonist to said cytokine or lymphokine.
- 18. The antigenic composition of Claim 1 where the selected antigen is from human immunodeficiency virus (HIV).
- 19. Th antig nic composition of Claim 18 where th selected HIV antigen is an HIV protein,

polypeptide, peptide or fragment derived from said protein.

20. The antigenic composition of Claim 19 where the selected antigens are the HIV peptides having the amino acid sequence:

Lys Gln Ile Ile Asn Met Trp Gln Glu Val Gly Lys Ala Met Tyr Ala Cys Thr Arg Pro Asn Tyr Asn Lys Arg Lys Arg Ile His Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr Lys (SEQ ID NO:1), or

Lys Gln Ile Ile Asn Met Trp Gln Glu Val Gly Lys Ala Met Tyr Ala Cys Thr Arg Pro Asn Tyr Asn Lys Arg Lys Arg Ile His Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr Lys (SEQ ID NO:2).

- 21. The antigenic composition of Claim 18 where 3-0-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 22. The antigenic composition of Claim 18 where the cytokine or lymphokine is selected from the group consisting of granulocyte macrophage colony stimulating factor and interleukin-12.
- 23. The antigenic composition of Claim 22 where the cytokine or lymphokine is granulocyte macrophage colony stimulating factor.
- 24. The antigenic composition of Claim 23 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 25. The antigenic composition of Claim 22 where the cytokine or lymphokine is interleukin-12.
- 26. The antigenic composition of Claim 25 where 3-0-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 27. The antigenic composition of Claim 18 which further comprises a diluent or carrier.

- 110 -

- 28. The antigenic composition of Claim 27 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 29. The antigenic composition of Claim 1 where the selected antigen is from simian immunodeficiency virus (SIV).
- 30. The antigenic composition of Claim 29 where the selected SIV antigen is an SIV protein, polypeptide, peptide or fragment derived from said protein.
- where the selected antigen is an SIV peptide selected from the peptides consisting of the amino acid sequences: Cys Thr Pro Tyr Asp Ile Asn Gln Met (SEQ ID NO:3), Ser Thr Pro Pro Leu Val Arg Leu Val (SEQ ID NO:4), Tyr Ala Pro Pro Ile Ser Gly Gln Ile (SEQ ID NO:5), Glu Leu Tyr Lys Tyr Lys Val Val Lys Ile Glu Pro Leu Gly Val Ala Pro Thr Lys Ala Cys Thr Pro Tyr Asp Ile Asn Gln Met (SEQ ID NO:7), Glu Leu Tyr Lys Val Val Lys Ile Glu Pro Leu Gly Val Ala Pro Leu Gly Val Ala Pro Thr Lys Ala Ser Thr Pro Pro Leu Val Arg Leu Val (SEQ ID NO:8) and Glu Leu Tyr Lys Tyr Lys Val Val Lys Ile Glu Pro Leu Gly Val Ala Pro Thr Lys Ala Ser Thr Pro Pro Lys Ala Tyr Ala Pro Pro Ile Ser Gly Gln Ile (SEQ ID NO:9).
- 32. The antigenic composition of Claim 29 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 33. The antigenic composition of Claim 29 where the cytokine or lymphokine is selected from the group consisting of granulocyte macrophage colony stimulating factor and interleukin-12.
- 34. The antigenic composition of Claim 33 where the cytokine or lymphokine is granulocyte macrophage colony stimulating factor.

- 111 -

- 35. The antigenic composition of Claim 34 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 36. The antigenic composition of Claim 33 where the cytokine or lymphokine is interleukin-12.
- 37. The antigenic composition of Claim 36 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 38. The antigenic composition of Claim 29 which further comprises a diluent or carrier.
- 39. The antigenic composition of Claim 38 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 40. The antigenic composition of Claim 1 where the selected antigen is from Neisseria gonorrhoeae.
- 41. The antigenic composition of Claim 40 where the selected Neisseria gonorrhoeae antigen is a Neisseria gonorrhoeae protein, polypeptide, peptide or fragment derived from said protein.
- 42. The antigenic composition of Claim 41 where the selected antigen is the Neisseria gonorrhoeae Porin B protein.
- 43. The antigenic composition of Claim 40 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 44. The antigenic composition of Claim 40 where the cytokine or lymphokine is selected from the group consisting of granulocyte macrophage colony stimulating factor and interleukin-12.
- 45. The antigenic composition of Claim 44 where the cytokine or lymphokine is granulocyte macrophage colony stimulating factor.

- 112 -

46. The antigenic composition of Claim 45 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.

- 47. The antigenic composition of Claim 44 where the cytokine or lymphokine is interleukin-12.
- 48. The antigenic composition of Claim 47 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 49. The antigenic composition of Claim 40 which further comprises a diluent or carrier.
- 50. The antigenic composition of Claim 49 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 51. The antigenic composition of Claim 1 where the selected antigen is from human Respiratory syncytial virus (RSV).
- 52. The antigenic composition of Claim 51 where the selected RSV antigen is an RSV protein, polypeptide, peptide or fragment derived from said protein.
- 53. The antigenic composition of Claim 52 where the selected antigen is the RSV fusion (F) protein.
- 54. The antigenic composition of Claim 51 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 55. The antigenic composition of Claim 51 where the cytokine or lymphokine is selected from the group consisting of granulocyte macrophage colony stimulating factor and interleukin-12.
- 56. The antigenic composition of Claim 55 wh re th cytokine or lymphokine is granulocyte macrophage colony stimulating factor.

- 57. The antigenic composition of Claim 56 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 58. The antigenic composition of Claim 55 where the cytokine or lymphokine is interleukin-12.
- 59. The antigenic composition of Claim 58 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 60. The antigenic composition of Claim 51 which further comprises a diluent or carrier.
- 61. The antigenic composition of Claim 60 where 3-O-deacylated monophosphoryl lipid A is used in the form of a stable oil-in-water emulsion.
- 62. A method for increasing the ability of an antigenic composition containing an HIV antigen to elicit the immune response of a vertebrate host, which comprises administering to said host an antigenic composition of Claim 18.
- 63. A method for increasing the ability of an antigenic composition containing an HIV antigen to elicit the immune response of a vertebrate host, which comprises administering to said host an antigenic composition of Claim 27.
- 64. The method of Claim 63 where the HIV antigen is the HIV peptide having the amino acid sequence:
- Lys Gln Ile Ile Asn Met Trp Gln Glu Val Gly Lys Ala Met Tyr Ala Cys Thr Arg Pro Asn Tyr Asn Lys Arg Lys Arg Ile His Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr Lys (SEQ ID NO:1).
- 65. The method of Claim 63 where the HIV antigen is the HIV peptide having the amino acid sequence:

Lys Gln Ile Ile Asn Met Trp Gln Glu Val Gly Lys Ala Met Tyr Ala Thr Arg Pro Asn Tyr Asn Lys Arg Lys Arg Ile His Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr Lys (SEQ ID NO:2).

- 66. A method for increasing the ability of an antigenic composition containing an HIV antigen to elicit cytotoxic T lymphocytes in a vertebrate host, which comprises administering to said host an antigenic composition of Claim 18.
- 67. A method for increasing the ability of an antigenic composition containing an HIV antigen to elicit cytotoxic T lymphocytes in a vertebrate host, which comprises administering to said host an antigenic composition of Claim 27.
- 68. The method of Claim 67 where the HIV antigen is the HIV peptide having the amino acid sequence:

Lys Gln Ile Ile Asn Met Trp Gln Glu Val Gly Lys Ala Met Tyr Ala Cys Thr Arg Pro Asn Tyr Asn Lys Arg Lys Arg Ile His Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr Lys (SEQ ID NO:1).

69. The method of Claim 67 where the HIV antigen is the HIV peptide having the amino acid sequence:

Lys Gln Ile Ile Asn Met Trp Gln Glu Val Gly Lys Ala Met Tyr Ala Thr Arg Pro Asn Tyr Asn Lys Arg Lys Arg Ile His Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr Lys (SEQ ID NO:2).

- 70. A method for increasing the ability of an antigenic composition containing an SIV antigen to elicit the immune response of a vertebrate host, which comprises administering to said host an antigenic composition of Claim 29.
- 71. A m thod for increasing the ability of an antigenic composition containing an SIV antigen to elicit the immune r sponse of a vertebrate host, which

comprises administering to said host an antigenic composition of Claim 38.

antigen is an SIV peptide selected from the peptides consisting of the amino acid sequences: Cys Thr Pro Tyr Asp Ile Asn Gln Met (SEQ ID NO:3), Ser Thr Pro Pro Leu Val Arg Leu Val (SEQ ID NO:4), Tyr Ala Pro Pro Ile Ser Gly Gln Ile (SEQ ID NO:5), Glu Leu Tyr Lys Tyr Lys Val Val Lys Ile Glu Pro Leu Gly Val Ala Pro Thr Lys Ala Cys Thr Pro Tyr Asp Ile Asn Gln Met (SEQ ID NO:7), Glu Leu Tyr Lys Tyr Lys Val Val Lys Ite Glu Pro Leu Gly Val Ala Pro Thr Lys Ala Pro Thr Lys Ala Ser Thr Pro Pro Leu Val Arg Leu Val (SEQ ID NO:8) and Glu Leu Tyr Lys Tyr Lys Val Val Lys Ite Glu Pro Leu Gly Val Glu Glu Pro Leu Gly Val Ala Pro Thr Lys Ala Pro Pro Leu Ser Gly Gln Ite (SEQ ID NO:9).

73. A method for increasing the ability of an antigenic composition containing an SIV antigen to elicit cytotoxic T lymphocytes in a vertebrate host, which comprises administering to said host an antigenic composition of Claim 29.

74. A method for increasing the ability of an antigenic composition containing an SIV antigen to elicit cytotoxic T lymphocytes in a vertebrate host, which comprises administering to said host an antigenic composition of Claim 38.

75. The method of Claim 74 where the SIV antigen is an SIV peptide selected from the peptides consisting of the amino acid sequences: Cys Thr Pro Tyr Asp Ile Asn Gln Met (SEQ ID NO:3), Ser Thr Pro Pro Leu Val Arg Leu Val (SEQ ID NO:4), Tyr Ala Pro Pro Ile Ser Gly Gln Ile (SEQ ID NO:5), Glu Leu Tyr Lys Tyr Lys Val Val Lys Ile Glu Pro Leu Gly Val Ala Pro Thr Lys Ala Cys Thr Pro Tyr Asp Ile Asn Gln Met (SEQ ID NO:7), Glu Leu Tyr Lys Tyr Lys Val Val Lys Ile Glu Pro Leu Gly Val Ala Pro Thr Lys Ala Ala Pro Thr Lys Ala Ser Thr Pro Pro Leu Val Arg Leu Val

- 116 -

(SEQ ID NO:8) and Glu Leu Tyr Lys Tyr Lys Val Val Lys Ile Glu Pro Leu Gly Val Ala Pro Thr Lys Ala Tyr Ala Pro Pro Ile Ser Gly Gln Ile (SEQ ID NO:9).

- 76. A method for increasing the ability of an antigenic composition containing a Neisseria gonorrhoeae antigen to elicit the immune response of a vertebrate host, which comprises administering to said host an antigenic composition of Claim 40.
- 77. A method for increasing the ability of an antigenic composition containing a Neisseria gonorrhoeae antigen to elicit the immune response of a vertebrate host, which comprises administering to said host an antigenic composition of Claim 49.
- 78. The method of Claim 77 where the Neisseria gonorrhoeae antigen is the Neisseria gonorrhoeae Porin B protein.
- 79. A method for increasing the ability of an antigenic composition containing a *Neisseria* gonorrhoeae antigen to elicit cytotoxic T lymphocytes in a vertebrate host, which comprises administering to said host an antigenic composition of Claim 40.
- 80. A method for increasing the ability of an antigenic composition containing a Neisseria gonorrhoeae antigen to elicit cytotoxic T lymphocytes in a vertebrate host, which comprises administering to said host an antigenic composition of Claim 49.
- 81. The method of Claim 80 where the Neisseria gonorrhoeae antigen is the Neisseria gonorrhoeae Porin B protein.
- 82. A method for increasing the ability of an antigenic composition containing a human Respiratory syncytial virus (RSV) antigen to elicit the immune response of a vertebrate host, which comprises administering to said host an antigenic composition of Claim 51.

- 117 -

83. A method for increasing the ability of an antigenic composition containing an RSV antigen to elicit the immune response of a vertebrate host, which comprises administering to said host an antigenic composition of Claim 60.

- 84. The method of Claim 83 where the RSV antigen is the RSV fusion (F) protein.
- 85. A method for increasing the ability of an antigenic composition containing an RSV antigen to elicit cytotoxic T lymphocytes in a vertebrate host, which comprises administering to said host an antigenic composition of Claim 51.
- 86. A method for increasing the ability of an antigenic composition containing an RSV antigen to elicit cytotoxic T lymphocytes in a vertebrate host, which comprises administering to said host an antigenic composition of Claim 60.
- 87. The method of Claim 86 where the RSV antigen is the RSV fusion (F) protein.